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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/607,766	06/27/2003	David Wynn	MCP-5014 NP	7412

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EXAMINER	
ROGERS, JAMES WILLIAM	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
04/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/607,766	WYNN ET AL.	
	Examiner	Art Unit	
	JAMES W. ROGERS	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,8-20,22 and 23* is/are pending in the application.

4a) Of the above claim(s) *6,13 and 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8-12 and 15-20,22 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Any rejection/objection from the previous office action filed 08/15/2007 not addressed in the action below has been withdrawn. The amendment to the claims filed 12/14/2007 has been entered, applicants have amended claims 1 and 22 and cancelled claim 21.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-5,8-12 and 15-20,22 and 23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically claims 1 and 22 lack written description because while the claims and specification state that no more than a certain percent of water is left after drying at 105 ^{o}C the time in which the dosage form is dried was not recited. Therefore claim 21 lacks written description because the amount of water remaining after drying at high temperature would depend upon the time it was dried; therefore applicants have not described their limitation in the claims or specification in sufficient detail to practice their claimed invention. This new rejection was necessitated by applicant's amendments to the claims.

Response to Arguments

Applicant's arguments filed 03/04/2008 have been fully considered but they are not persuasive. Applicants have cancelled claim 21 but the limitation within the claim is now part of claims 1 and 22, thus applicants arguments are relevant to the new rejection above that was necessitated by amendment. Applicants assert the time required to dry the dosage form will depend upon the formulation of the dosage form e.g. the water content of the dosage form at room temperature, thus the time to dry cannot be determined.

The relevance of this assertion is unclear. Applicants appear to argue that since the formulation of the dosage form is not described in enough detail within the claims or specification it would not be possible to deduce the time necessary to dry the dosage form. Rather then refute the examiners argument applicants may instead have actually bolstered the argument by the examiner since by applicants admission one can not determine the time to dry a formulation unless the exact formulation is described. Thus since the time to dry the dosage form cannot be determined from the description within the claims or specification the limitation that the dosage form has a moisture content of not more than about 5 percent as measured by weight loss on drying at 105 degrees Celsius is not described in sufficient detail for one of ordinary skill to practice applicants claimed invention. In order for one to measure the moisture content present within a dosage form the time and temperature at which it is dried is essential information to practice the analysis since inherently the amount of moisture left upon drying will depend on the time and temperature.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5,8-12 and 15-20,22 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buehler et al. (US 6,432,442 B1) in view of McTeigue et al (US 2002/0031552 A1) in view of Dressman et al (US 5,789,393).

Applicant's arguments filed 03/04/2008 have been fully considered but they are not persuasive.

Applicants assert that Buehler does not describe an immediate release compressed tablet that has a moisture content of not more than about 5 percent as measured by weight loss on drying at 105°C. To bolster this argument applicants cite that Buehler discloses the use of a gelatin matrix for providing a soft chewable delivery system and the dosage form must contain water in an amount from about 10 to 30 percent by weight of the final product.

The relevance of the above assertions is unclear. Clearly Buehler states that the compositions are soft chewable pharmaceutical dosage forms and that pharmaceutical and nutritional supplement dosage forms intended for oral administration are typically provided by tablet form that is swallowed whole, chewed in the mouth or dissolved sublingually. See col 1 lin 4-23. Regarding applicants assertion on the moisture content being no more than 5% after drying, it is important to note that the limitation does not actually state that the moisture content is not more than about 5% for the claimed composition, instead the limitation is a functional limitation for the composition that

states it has a moisture content of no more than **5% after drying**. Since by combination the references teach the same composition as claimed by applicant it is inherent that the same composition will have the same moisture content when dried at 105°C for an unspecified length of time. If the composition formed from the combination of references was dried to completion at 105°C the examiner concludes that the moisture content would be less then 5% since the composition is essentially the same as applicants claimed composition and would therefore have the same drying properties. Furthermore it is noted as stated above that there is no actual recitation of the time the composition was dried, thus almost any conceivable composition when exposed to temperatures of 105°C, which is of course higher than the bp of water would contain essentially little or no moisture if dried for extremely long periods of time.

Applicants further assert that while Dressman may disclose the use of specific MW HPC as claimed the reference does not disclose or suggest the use of such ingredient in a chewable tablet, thus there would be no reasonable expectation of success in combining the HPC of Dressman with the HPC of Buehler.

The examiner respectfully disagrees with the above assertion. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Dressman was used as a secondary reference only to show that HPC within the MW and viscosity claimed by applicant was well known at the time of the invention. Clearly since Bueler

describes HPC in the use of chewable matrixes, one of ordinary skill in the art would have a reasonable expectation of success in using the specific HPC described in Dressman, since both references are at least related as pertaining to pharmaceutical formulations and it would be expected that natural polymers that are the same such as HPC could be interchanged between the two references.

Applicants lastly assert that they have found unexpected results when using the HPC within the specific amount and MW claimed because they were found to have a good mouthfeel without the intense drying sensation or subsequent slimy or gummy feel during mastication.

The examiner notes that the above cited unexpected result is actually just a subjective analysis or opinion of the benefits of the HPC matrix claimed and there is no actual evidence besides the above conclusionary statement that demonstrates or describes the above benefits or unexpected result. A showing of unexpected results must be based on evidence, not argument or speculation. In re Mayne, 104 F.3d 1339, 1343-44, 41 USPQ2d 1451, 1455-56 (Fed. Cir. 1997) (conclusory statements that claimed compound possesses unusually low immune response or unexpected biological activity that is unsupported by comparative data held insufficient to overcome prima facie case of obviousness). Thus applicants have only described an opinion or subjective analysis on the mouthfeel and non-dry or subsequent gummy or slimy feel, thus the conclusionary statement above is not considered to contain enough evidence to remove the prior art rejection under 103(a). See **MPEP §716.02-716.02(g)** for an analysis of allegations of unexpected results.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618

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	10/607,766	WYNN ET AL.	
	Examiner	Art Unit	
	JAMES W. ROGERS	1618	